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**XANAX® Tablets G**  
(alprazolam)

**CONTRAINDICATIONS**

Patients with sensitivity to this drug or other benzodiazepines and in acute narrow angle glaucoma.

**WARNINGS**

Not of value in psychotic patients. Caution patients against hazardous occupations requiring complete mental alertness and about the simultaneous ingestion of alcohol and other CNS depressant drugs.

Benzodiazepines can cause fetal harm in pregnant women. Warn patients of the potential hazard to the fetus. Avoid during the first trimester.

**PRECAUTIONS**

**General:** If XANAX is combined with other psychotropics or anti-convulsant drugs, consider drug potentiation (see Drug Interaction section). Exercise the usual precautions regarding size of the prescription for depressed or suicidal patients. In elderly and debilitated patients, use the lowest possible dosage (see Dosage and Administration). Observe the usual precautions in treating patients with impaired renal or hepatic function.

**Information for Patients:** Alert patients about (a) consumption of alcohol and drugs, (b) possible fetal abnormalities, (c) operating machinery or driving, (d) not increasing dose of the drug due to risk of dependence, (e) not stopping the drug abruptly. **Laboratory Tests:** Not ordinarily required in otherwise healthy patients. **Drug Interactions:** Additive CNS depressant effects with other psychotropics, anticonvulsants, antihistamines, ethanol and other CNS depressants. Pharmacokinetic interactions with benzodiazepines have been reported. **Drug/Laboratory Test Interactions:** No consistent pattern for a specific drug or specific test. **Carcinogenesis, Mutagenesis, Impairment of Fertility:** No carcinogenic potential or impairment of fertility in rats. **Pregnancy:** See Warnings. **Nonteratogenic Effects:** The child born of a mother on benzodiazepines may be at some risk for withdrawal symptoms and neonatal flaccidity. **Labor and Delivery:** No established use. **Nursing Mothers:** Benzodiazepines are excreted in human milk. Women on XANAX should not nurse. **Pediatric Use:** Safety and effectiveness in children below the age of 18 have not been established.

**ADVERSE REACTIONS**

Side effects are generally observed at the beginning of therapy and usually disappear with continued medication. In the usual patient the most frequent side effects are likely to be an extension of the pharmacological activity of XANAX, e.g., drowsiness or lightheadedness.

**Central Nervous System:** Drowsiness, lightheadedness, depression, headache, confusion, insomnia, nervousness, syncope, dizziness, akathisia, and tiredness/sleepiness.

**Gastrointestinal:** Dry mouth, constipation, diarrhea, nausea/vomiting, and increased salivation.

**Cardiovascular:** Tachycardia/palpitations, and hypotension.

**Sensory:** Blurred vision.

**Musculoskeletal:** Rigidity and tremor.

**Cutaneous:** Dermatitis/allergy.

**Other Side Effects:** Nasal congestion, weight gain, and weight loss.

In addition, the following adverse events have been reported with the use of anxiolytic benzodiazepines: dystonia, irritability, concentration difficulties, anorexia, loss of coordination, fatigue, sedation, slurred speech, jaundice, musculoskeletal weakness, pruritus, diplopia, dysarthria, changes in libido, menstrual irregularities, incontinence and urinary retention.

Paradoxical reactions such as stimulation, agitation, increased muscle spasticity, sleep disturbances, and hallucinations may occur. Should these occur, discontinue the drug.

During prolonged treatment period: blood counts, urinalysis, and blood chemistry analyses are advisable. Minor EEG changes, of unknown significance, have been observed.

**DRUG ABUSE AND DEPENDENCE**

**Physical and Psychological Dependence:** Withdrawal symptoms have occurred following abrupt discontinuance of benzodiazepines. After prolonged therapy, dosage should be tapered. **Controlled Substance Class:** XANAX is a controlled substance and has been assigned to schedule IV.

**CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION.**

BS-1

\*Cohn JB: Multicenter double-blind efficacy and safety study comparing alprazolam, diazepam and placebo in clinically anxious patients. *J Clin Psychiatry* 42 (9):347-351, 1981.

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# SYMMETREL<sup>®</sup> 100 MG CAPSULES (AMANTADINE HCl)

## BRIEF SUMMARY OF PRESCRIBING INFORMATION

**INDICATIONS.** Parkinson's Disease/Syndrome and Drug-Induced Extrapyramidal Reactions. SYMMETREL is indicated in the treatment of idiopathic Parkinson's disease (Paralysis Agitans), postencephalitic parkinsonism, drug-induced extrapyramidal reactions, and symptomatic parkinsonism which may follow injury to the nervous system by carbon monoxide intoxication. It is indicated in those elderly patients believed to develop parkinsonism in association with cerebral arteriosclerosis. In the treatment of Parkinson's disease, SYMMETREL is less effective than levodopa. (-)-3-(3,4-dihydroxyphenyl)-L-alanine, and its efficacy in comparison with the anticholinergic antiparkinson drugs has not yet been established. Although anticholinergic type side effects have been noted with SYMMETREL when used in patients with drug-induced extrapyramidal reactions, there is a lower incidence of these side effects than that observed with anticholinergic antiparkinson drugs.

**CONTRAINDICATIONS.** SYMMETREL is contraindicated in patients with known hypersensitivity to the drug.

**WARNINGS.** Patients with a history of epilepsy or other "seizures" should be observed closely for possible increased seizure activity.

Patients with a history of congestive heart failure or peripheral edema should be followed closely as there are patients who developed congestive heart failure while receiving SYMMETREL.

Patients with Parkinson's disease improving on SYMMETREL should resume normal activities gradually and cautiously consistent with other medical considerations, such as the presence of osteoporosis or phlebotomiasis.

Patients receiving SYMMETREL who note central nervous system effects or blurring of vision should be cautioned against driving or working in situations where alertness is important.

**PRECAUTIONS.** SYMMETREL (amantadine hydrochloride) should not be discontinued abruptly since a few patients with Parkinson's disease experienced a parkinsonian crisis, i.e., a sudden marked clinical deterioration, when this medication was suddenly stopped. The dose of anticholinergic drugs or of SYMMETREL should be reduced if atropine-like effects appear when these drugs are used concurrently.

The dose of SYMMETREL may need careful adjustment in patients with renal impairment, congestive heart failure, peripheral edema, or orthostatic hypotension. Since SYMMETREL is not metabolized and is mainly excreted in the urine, it may accumulate when renal function is inadequate.

Care should be exercised when administering SYMMETREL to patients with liver disease, a history of recurrent eczematoid rash, or to patients with psychosis or severe psychoneurosis not controlled by chemotherapeutic agents. Careful observation is required when SYMMETREL is administered concurrently with central nervous system stimulants.

No long-term studies in animals have been performed to evaluate the carcinogenic potential of SYMMETREL. The mutagenic potential of the drug has not yet been determined in experimental systems.

**Pregnancy Category C:** SYMMETREL (amantadine hydrochloride) has been shown to be embryotoxic and teratogenic in rats at 50 mg/kg/day, about 12 times the recommended human dose, but not at 37 mg/kg/day. Embryotoxic and teratogenic drug effects were not seen in rabbits which received up to 25 times the recommended human dose. There are no adequate and well-controlled studies in pregnant women.

SYMMETREL should be used during pregnancy only if the potential benefit justifies the potential risk to the embryo or the fetus.

**Nursing Mothers:** SYMMETREL is excreted in human milk. Caution should be exercised when SYMMETREL is administered to a nursing woman.

**Pediatric Use:** The safety and efficacy of SYMMETREL in newborn infants, and infants below the age of 1 year have not been established.

**ADVERSE REACTIONS.** The most frequently occurring serious adverse reactions are depression, congestive heart failure, orthostatic hypotensive episodes, psychosis, and urinary retention. Rarely convulsions, leukopenia, and neutropenia have been reported.

Other adverse reactions of a less serious nature which have been observed are the following: hallucinations, confusion, anxiety and irritability, anorexia, nausea, and constipation; ataxia and dizziness (lightheadedness), livedo reticularis and peripheral edema. Adverse reactions observed less frequently are the following: vomiting, dry mouth, headache, dyspnea, fatigue, insomnia, and a sense of weakness. Infrequently skin rash, slurred speech, and visual disturbances have been observed. Rarely eczematoid dermatitis and oculogyric episodes have been reported.

**DOSE AND ADMINISTRATION. Adult Dosage for Parkinsonism:** The usual dose of SYMMETREL (amantadine hydrochloride) is 100 mg twice a day when used alone. SYMMETREL has an onset of action usually within 48 hours.

The initial dose of SYMMETREL is 100 mg daily for patients with serious associated medical illnesses or who are receiving high doses of other antiparkinson drugs. After one to several weeks at 100 mg once daily, the dose may be increased to 100 mg twice daily if necessary.

Occasionally patients whose responses are not optimal with SYMMETREL at 200 mg daily may benefit from an increase up to 400 mg daily in divided doses. However, such patients should be supervised closely by their physicians.

Patients initially deriving benefit from SYMMETREL not uncommonly experience a fall-off of effectiveness after a few months. Benefit may be regained by increasing the dose to 300 mg daily. Alternatively, temporary discontinuation of SYMMETREL for several weeks, followed by reinitiation of the drug, may result in regaining benefit in some patients. A decision to use other antiparkinson drugs may be necessary.

**Dosage for Concomitant Therapy:** Some patients who do not respond to anticholinergic antiparkinson drugs may respond to SYMMETREL. When SYMMETREL or anticholinergic antiparkinson drugs are each used with marginal benefit, concomitant use may produce additional benefit.

When SYMMETREL and levodopa are initiated concurrently the patient can exhibit rapid therapeutic benefits. SYMMETREL should be held constant at 100 mg daily or twice daily while the daily dose of levodopa is gradually increased to optimal benefit.

When SYMMETREL is added to optimal well-tolerated doses of levodopa, additional benefit may result, including smoothing out the fluctuations in improvement which sometimes occur in patients on levodopa alone. Patients who require a reduction in their usual dose of levodopa because of development of side effects may possibly regain lost benefit with the addition of SYMMETREL.

**Dosage for Drug-Induced Extrapyramidal Reactions:** Adult: The usual dose of SYMMETREL (amantadine hydrochloride) is 100 mg twice a day. Occasionally patients whose responses are not optimal with SYMMETREL at 200 mg daily may benefit from an increase up to 300 mg daily in divided doses.

6043-10BSP

Capsules manufactured by R.P. Scherer-North America, St. Petersburg, Florida 33702 for

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## Prescribing information

**INDICATIONS** — For management of anxiety disorders or short-term relief of symptoms of anxiety: for symptomatic relief of acute alcohol withdrawal: for adjunctive therapy in partial seizures.

Anxiety or tension associated with stress of everyday life usually does not require treatment with an anxiolytic. Effectiveness in long-term management of anxiety (over 4 months) not assessed by systematic clinical studies. The physician should periodically reassess usefulness for each patient.

**CONTRAINDICATIONS** — Known hypersensitivity to the drug. Acute narrow angle glaucoma.

**WARNINGS** — Not recommended for use in depressive neuroses or psychotic reactions. Caution patient against hazardous occupations requiring mental alertness, such as operating dangerous machinery including motor vehicles. Advise against simultaneous use of other CNS depressants, and caution patients that effects of alcohol may be increased. Not recommended for patients under 9. Nervousness, insomnia, irritability, diarrhea, muscle aches, and memory impairment have followed abrupt withdrawal from long-term high dosage. Withdrawal symptoms were reported after abrupt discontinuance of benzodiazepines taken continuously at therapeutic levels for several months. Use caution in patients having psychological potential for drug dependence (dependence has been observed in dogs and rabbits).

**Pregnancy and Lactation:** Minor tranquilizers should almost always be avoided first trimester. Consider possibility of pregnancy before initiating therapy. Patient should consult physician about discontinuation if she becomes pregnant or plans pregnancy. Do not give to nursing mothers.

**PRECAUTIONS** — Observe usual precautions in depression accompanying anxiety, or in patients with suicidal tendency, or those with impaired renal or hepatic function. Do periodic blood counts and liver function tests during prolonged therapy. Use small doses and gradual increments in the elderly or debilitated.

**ADVERSE REACTIONS** — Drowsiness, dizziness, various g.i. complaints, nervousness, blurred vision, dry mouth, headache, mental confusion, insomnia, transient skin rashes, fatigue, ataxia, genitourinary complaints, irritability, diplopia, depression, slurred speech, abnormal liver and kidney function tests, decreased hematocrit, decreased systolic blood pressure.

**INTERACTIONS** — Potentiation may occur with ethyl alcohol, hypnotics, barbiturates, narcotics, phenothiazines, MAO inhibitors, other antidepressants. In bioavailability studies with normal subjects, concurrent administration of antacids at therapeutic levels did not significantly influence bioavailability of TRANXENE.

**OVERDOSAGE** — Take general measures as for any CNS depressant.

**SUPPLIED** — TRANXENE 3.75, 7.5, and 15 mg capsules and scored tablets. TRANXENE-SD Half Strength 11.25 and TRANXENE-SD 22.5 mg single dose tablets.

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